

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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15 JUL 2010

FILE No.

45480

G.E. EHRLICH (1995) LTD.

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing

(day/month/year)

15.07.2010

Applicant's or agent's file reference

45480

IMPORTANT NOTIFICATION

International application No.

PCT/IL2009/000443

International filing date (day/month/year)

23.04.2009

Priority date (day/month/year)

23.04.2008

Applicant

Contipi Ltd.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 45480	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IL2009/000443	International filing date (day/month/year) 23.04.2009	Priority date (day/month/year) 23.04.2008	
International Patent Classification (IPC) or national classification and IPC INV. A61F2/00			
Applicant Contipi Ltd.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of <u>5</u> sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3bis of Annex C of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 2010-02-22		Date of completion of this report 15.07.2010	
Name and mailing address of the international preliminary examining authority:  European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016		Authorized officer Neumann, Elisabeth Telephone No. +31 70 340-3028 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2009/000443

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-42 as originally filed

Claims, Numbers

1-30 filed with telefax on

05-07-2010

Drawings, Sheets

1/33-33/33 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2 (e)).
6. ☐ Supplementary international search report(s) from Authority(ies) have been received and taken into account in drawing up this report (Rule 45bis.8(b) and (c)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2009/000443

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-30</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-30</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-30</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 WO 2006/097935 A2 (CONTIPI LTD [IL]; SINAI NIR [IL]; ZIV ELAN [IL]; BUDER IDAN [IL]; GILA) 21 September 2006 (2006-09-21)
- D2 WO 2008/010214 A2 (CONTIPI LTD [IL]; ZIV ELAN [IL]; GILAN JACOB [IL]; SINAI NIR [IL]; BAU) 24 January 2008 (2008-01-24)
- D3 WO 2004/103213 A (CONTIPI LTD [IL]; ZIV ELAN [IL]) 2 December 2004 (2004-12-02)
- D4 WO 03/047476 A1 (NISSENKORN ABRAHAM [IL]) 12 June 2003 (2003-06-12)
- D5 DE 271 657 C (LEVY) 17 March 1914 (1914-03-17)

1 INDEPENDENT CLAIMS 1, 28 AND 30

1.1 Document D4 is regarded as being the prior art closest to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A vaginal pessary (2) sized and shaped for alleviating organ prolapse (page 1, lines 2 - 3), comprising:

(a) a substantially planar body (4) including at least two rib sections (12a and 13a, 12b and 13b) adapted to, at least in one state, extend *perpendicular* to a vaginal axis (page 3, line 28 - page 4, line 2), wherein said body is adapted to be in at least two states:

(i) a compressed state (figs. 1A, 2A) in which said body is sized for insertion into said vagina; and

(ii) an expanded state (figs. 1B, 2B) in which said body is sized and stiff enough for providing organ prolapse alleviation and in which state said ribs extend *perpendicular* to a vaginal axis; and

(b) a state changing mechanism (26A, 26B) integral to said pessary and configured to change a configuration of said body from one state to the other state, which mechanism does not use fluid flow (it uses a mechanical ratchet mechanism: figures 2A, 2B) to cause state change, wherein said pessary is stable in shape and size in both states.

The subject-matter of claim 1 therefore differs from this known device in that the body is adapted to, at least in one state to extend along a vaginal axis and apply force to facing vaginal walls along axial extents thereof.

Claim 1 is therefore new (Article 33(2) PCT).

1.2 The problem to be solved by the present invention may be regarded as to substantially alleviate prolapse of at least one pelvic organ..

1.3 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Document D4 explicitly teaches to vary the distance between the two rib sections in the direction of the circumference of the body. No hint is given to extend the direction along the vaginal axis and it can also not be seen as a normal design option.

Another prior art document is WO-A-2005/087153 (D6) which is cited by the applicant. Especially for claim 30 (see point 1.6), document D6 discloses in figures 2A-C and page 10, lines 12 - 19 a substantially planar body comprising a frame formed of at least one elongate thin element. However, the device is provided with varying stiffness along its length and thus does not comprise a state changing mechanism integral to said pessary as claimed.

The other documents cited in the search report disclose pessaries comprising non-planar bodies. A combination of any of these documents would not lead the skilled person to the invention as claimed.

1.4 Claims 2 - 27 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

1.5 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent system claim 28 comprising the pessary of claim 1 and an applicator, which therefore is also considered new and inventive.

1.6 Claim 30 is directed to a vaginal pessary which differs from claim 1 in that the substantially planar body comprises a frame formed of at least one elongate thin element instead of the at least two rib sections. Claim 30 is therefore considered as an alternative solution to the same problem, whereby it is inappropriate to cover this alternative by a single claim.

Claim 30 is therefore considered new over the prior art.

As far as the inventive step reasoning is concerned see points 1.2 and 1.3 above.

Re Item VII

Certain defects in the international application

1 Independent claims 1 and 30 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D4) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D4 is not mentioned in the description, nor is this document identified therein.

CLAIMS

1. A vaginal pessary sized and shaped for alleviating organ prolapse, comprising:
 - (a) a substantially planar body including at least two rib sections adapted to, at least in one state, extend along a vaginal axis and apply force to facing vaginal walls along axial extents thereof, wherein said body is adapted to be in at least two states:
 - (i) a compressed state in which said body is sized for insertion into said vagina; and
 - (ii) an expanded state in which said body is sized and stiff enough for providing organ prolapse alleviation and in which state said ribs extend along a vaginal axis and apply force to facing vaginal walls; and
 - (b) a state changing mechanism integral to said pessary and configured to change a configuration of said body from one state to the other state, which mechanism does not use fluid flow to cause state change,
wherein said pessary is stable in shape and size in both states.
2. A pessary according to claim 1, wherein said ribs are adapted to contact said walls for a length of at least 30% of a length of said body along said vaginal axis.
3. A pessary according to claim 1 or claim 2, wherein said ribs are supported at either end thereof by said body.
4. A pessary according to any of the preceding claims, wherein said ribs state change mechanism spaces apart said ribs during a change from said compressed state to said expanded state.
5. A pessary according to any of the preceding claims, wherein said body in said expanded state alleviates organ prolapse by directly supporting a prolapsed organ.

6. A pessary according to any of the preceding claims, wherein said body is substantially rigid in said expanded state.
7. A pessary according to claim 6, wherein said body includes at least one flexible section at at least one of said states.
8. A pessary according to any of the preceding claims, wherein said state changing mechanism locks said pessary in at least one of said two states.
9. A pessary according to claim 8, wherein said state changing mechanism locks said pessary in both of said states.
10. A pessary according to any of the preceding claims, comprising at least one elastic element which urges said pessary towards at least one of said states.
11. A pessary according to any of the preceding claims, wherein said state changing mechanism is configured to become dysfunctional after a number of state changes.
12. A pessary according to claim 1, wherein said two spaced apart rib sections are substantially parallel.
13. A pessary according to any of the preceding claims, wherein said body is a closed shape including said two rib sections.
14. A pessary according to any of the preceding claims, wherein said body is ring-like.
15. A pessary according to claim 14, wherein said body comprises at least two arc sections connected by joints.

16. A pessary according to any of the preceding claims, wherein said body defines a border and comprising at least one membrane stretched on at least part of said border.
17. A pessary according to any of the preceding claims, wherein said body includes at least one lockable joint enclosed thereby.
18. A pessary according to any of the preceding claims, wherein said state changing mechanism is at least mostly enclosed by said body.
19. A pessary according to any of claims 1-17, wherein said state changing mechanism is at least mostly unenclosed by said body.
20. A pessary according to claim 19, wherein said state changing mechanism is parallel to said vaginal axis.
21. A pessary according to claim 19, wherein said state changing mechanism is perpendicular to said vaginal axis.
22. A pessary according to any of the preceding claims, wherein said state changing mechanism comprises a ratchet mechanism.
23. A pessary according to any of the preceding claims, wherein said state changing mechanism comprises a locking element and an elastic element pre-configured to move said locking element to a locking condition.
24. A pessary according to any of the preceding claims, comprising a control coupled to said state-changing element and configured to activate a state change when said control is pulled when inside a body.

25. A pessary according to any of the preceding claims, wherein said pessary is functionally rotationally symmetric around said vaginal axis.
26. A pessary according to any of the preceding claims, wherein said body consists essentially of one or more rods.
27. A pessary according to any of the preceding claims, wherein said body allows flow of vaginal secretions therepast.
28. A pessary system comprising:
(a) a substantially planar shape changing pessary according to any of claims 1-27 and adapted to alleviate organ prolapse when deployed in a vagina; and
(b) an applicator adapted for holding said pessary in a tension reduced compressed state while in a form suitable for insertion into a vagina.
29. A pessary system according to claim 28, wherein said applicator is configured to actively change a shape of said pessary after insertion thereof into a vagina.
30. A vaginal pessary sized and shaped for alleviating organ prolapse, comprising:
(a) a substantially planar body comprising a frame formed of at least one elongate thin element and adapted to, at least in one state, extend along a vaginal axis and apply force to facing vaginal walls along axial extents thereof, wherein said body is adapted to be in at least two states:
(i) a compressed state in which said body is sized for insertion into said vagina; and
(ii) an expanded state in which said body is sized and stiff enough for providing organ prolapse alleviation and in which state said frame extends along a vaginal axis and applies force to facing vaginal walls; and

(b) a state changing mechanism integral to said pessary and configured to change a configuration of said body from one state to the other state, which mechanism does not use fluid flow to cause state change.